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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,400	06/27/2003	Michael J. Pugia	017191.0042 (MSA-3453)	7945

7590 08/11/2006

Bayer Healthcare LLC
511 Benedict Avenue
Tarrytown, NY 10591

EXAMINER	
SINES, BRIAN J	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,400	PUGIA ET AL.	
	Examiner	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9,11-16 and 27-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9,11-16 and 27-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 8 are provisionally rejected on the ground of nonstatutory double patenting over claims 1 – 6 and 8 of copending Application No. 10/608,671. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The claimed device of the instant application appears to be identical to the device claimed in the copending application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

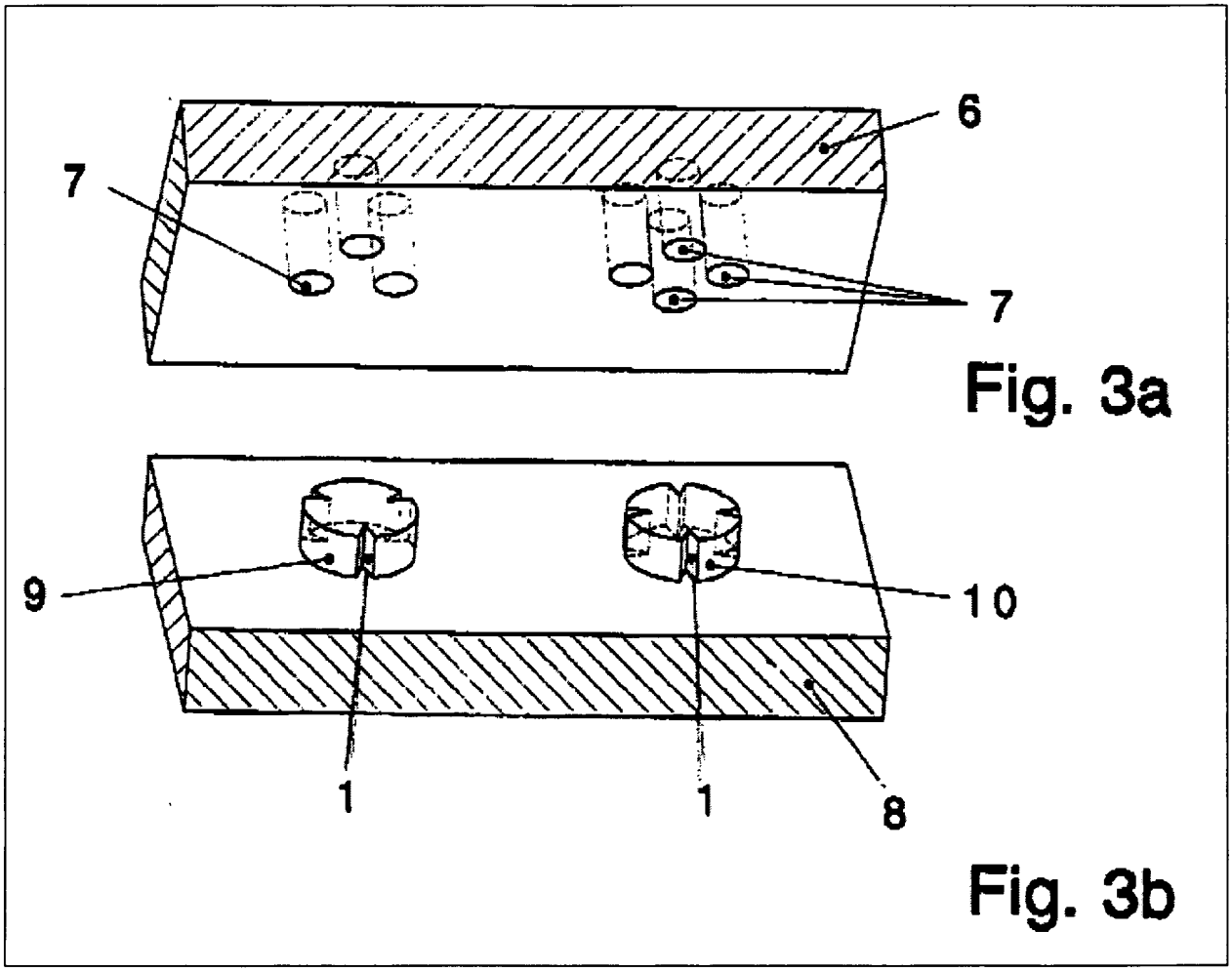
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 3 – 6 and 11 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over admitted prior art (the preamble to claim 1) in view of Peters (U.S. Pat. No. 6,296,126 B1) (hereinafter "Peters").

Claim 1 is written in Jepson claim format in which the claim recitation prior to the statement "the improvement comprising" is considered admitted prior art (see MPEP § 2129). Thus, the admitted prior art teaches a microfluidic device for assaying a liquid biological sample of 10 μ or less, wherein the device comprises at least one well in which a reagent or conditioning reagent is immobilized on a substrate placed inside the well, and wherein the well comprises an entry for a sample at a side thereof from a capillary passageway.

The admitted prior art does not teach the incorporation of a uniform array of posts and a vent.

Peters teaches an apparatus comprising a uniform array of posts (e.g., columnar projection 2) and a vent opening (36) that serves to uniformly distribute or wet the interior surface of the apparatus to facilitate effective optical analysis (see, e.g., col. 3, line 7 – col. 4, line 14; col. 4, lines 50 – 67; col. 6, lines 14 – 32; col. 6, lines 58 – 67; col. 7, lines 1 – 22; figures 3a, 3b, 7b & 8).



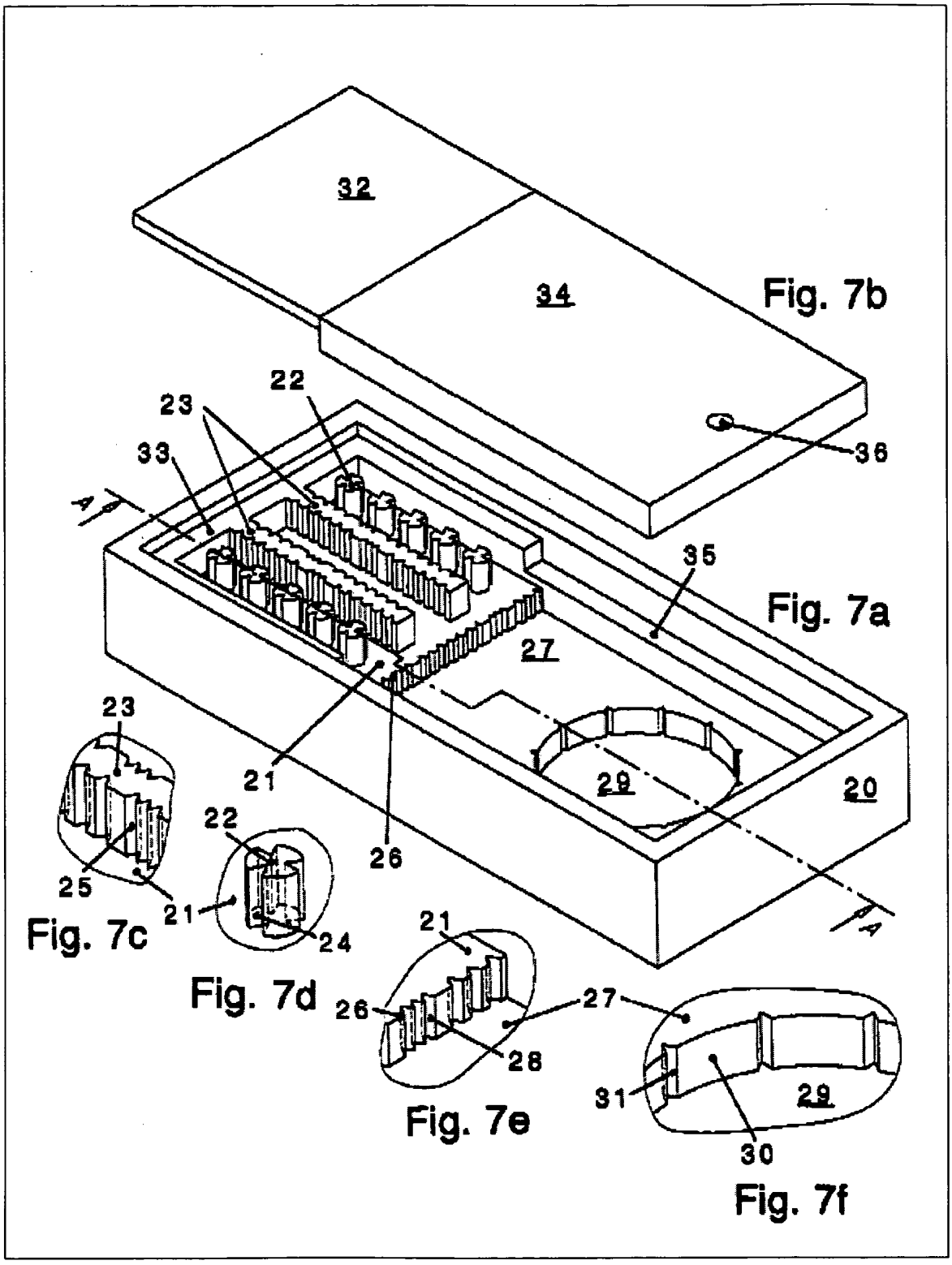

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Fig. 7b
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Fig. 7a
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Fig. 7c
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Fig. 7f

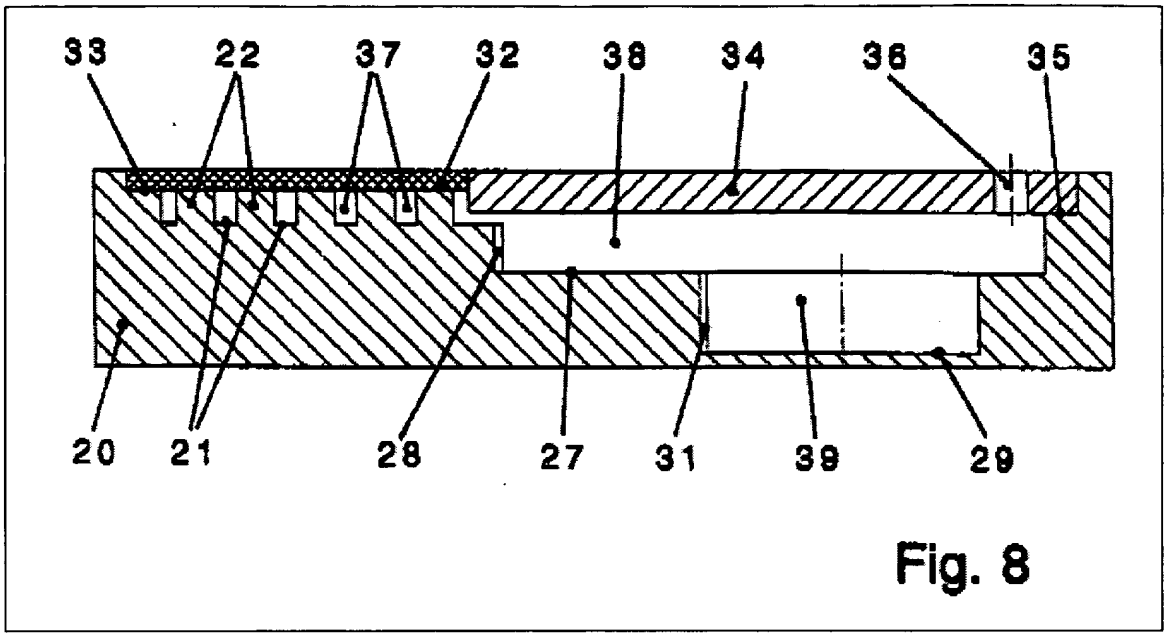


Fig. 8

Peters teaches that the device structural configuration has the advantage of enabling the collection of a free-flowing liquid in the microliter region (see col. 4, lines 5 – 14). Thus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of these post structures and associated vent for facilitating the effective uniform distribution or wetting of a sample fluid within the disclosed device for enabling optical analysis (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the post array and vent structures with the disclosed device as claimed in order to facilitate effective device operation.

Regarding claim 3, Peters teaches that the posts or columnar projections 22 may be arranged in any desired spatial arrangement and including a plurality of secondary posts (e.g., 23 & a second set of columnar projections 22 (not labeled) as shown in figure 7b (see col. 6, lines 58 – 67; figure 7b).

Regarding claim 4, Peters teaches the incorporation of wedge-shaped cut-outs 1 within the posts 2 (see col. 4, lines 50 – 67; figure 1a).

Regarding claims 5 and 6, Peters teaches that the posts 22 can be arranged on top of or above and in contact with a substrate portion (e.g., the surface of base 21) (see figures 7a and 7b).

Regarding claims 9 and 11 – 14, as discussed above, the admitted prior art and Peters teaches all of the positively recited structural limitations of the device provided in the claimed method. Peters teaches that the action of the device is based on the suction action of the wedge-shaped cut-outs in drawing sample fluid into the collecting chamber (see, e.g., col. 3, line 56 – col. 4, line 14; col. 7, lines 1 – 22). Peters indicates that the sample liquid enters the collecting chamber in a uniform or defined layer in a sufficient thickness suitable for optical analysis. Peters teaches that the displaced air escapes via the vent opening 36 as the sample liquid enters the chamber (see, e.g., col. 6, liens 14 – 32). Therefore, it would have been obvious to a person of ordinary skill in the art to employ the claimed method with the device taught by the prior art in order to facilitate effective sample analysis.

2. Claims 7, 8, 15 and 27 – 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art and Peters, and further in view of Columbus (U.S. Pat. No. 4,233,029).

Regarding claim 7, Columbus teaches an analytical apparatus comprising similar structures to posts for facilitating uniform sample fluid distribution within the apparatus. Columbus also teaches the incorporation of a microstructure (truncated ridges 46) comprising a

ramp or slanted or inclined portion and a substrate plateau (e.g., the flat top surface of the truncated ridge 46) (see col. 8, lines 1 – 67; figure 7a). Hence, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating these similar ramps structures for the similar intended purpose of enabling uniform sample fluid distribution or wetting within the device. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the a ramp with a substrate as claimed.

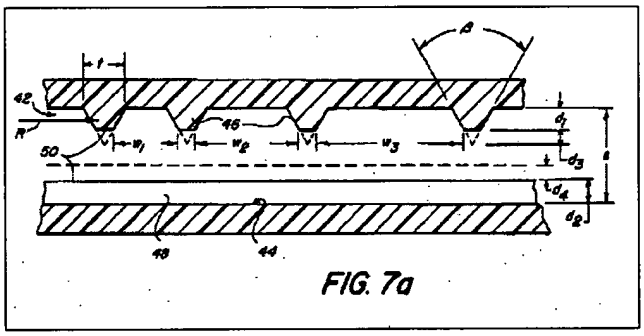
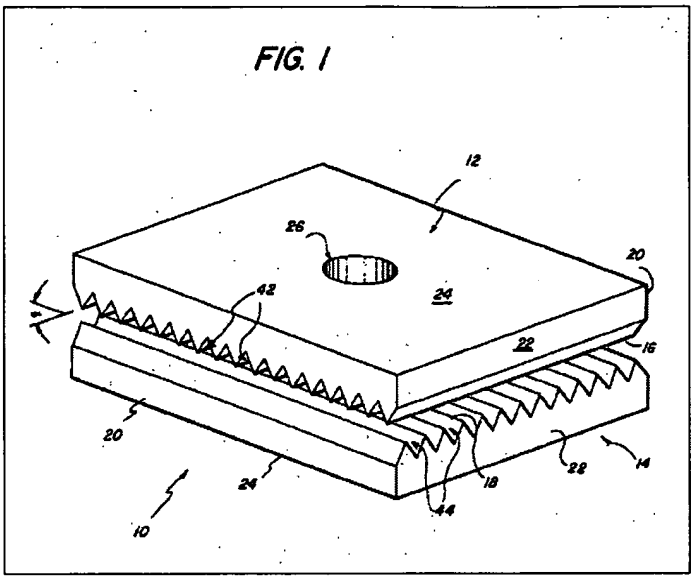


FIG. 7a

Regarding claim 8, Columbus teaches an analytical apparatus (10) comprising: at least one space (e.g., the space between interior surfaces 16 & 18) for containing a test sample and a reagent on a substrate (e.g., the bottom surface 18); a microstructure (grooves 42 & 44) disposed in the space for directing the test sample over the substrate in a uniform manner. As fluid is introduced into the space via port 26, the introduced fluid would displace and thereby purge any air contained within this space during use (see col. 3, line 16 – col. 4, line 68; figure 1). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a groove structure for facilitating the uniform distribution of sample fluid within the device.



Regarding claims 15, 16 and 27 – 32, as discussed above, the cited prior art teaches all of the positively recited structural limitations of the device provided in the claimed method. In particular, Columbus also teaches the incorporation of a microstructure (truncated ridges 46) comprising a ramp or slanted or inclined portion and a substrate plateau (e.g., the flat top surface of the truncated ridge 46) (see col. 8, lines 1 – 67; figure 7a). Columbus also teaches the incorporation of groove structures 42 (see figure 1). Therefore, it would have been obvious to a person of ordinary skill in the art to employ the claimed method with the device taught by the prior art in order to facilitate effective sample analysis.

Response to Arguments

Applicant's arguments with respect to the present claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).